UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804**
THIS DOCUMENT RELATES TO:	**Case No. 17-md-2804**
Track Seven	**Judge Dan Aaron Polster**

KROGER DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO EXCLUDE CERTAIN OPINIONS OF PATRICK J. MARSHALEK

Defendants The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II (hereafter collectively referred to as "Kroger"), by and through counsel, hereby submit their response in opposition to Plaintiff's Motion to Exclude Certain Opinions of Patrick J. Marshalek [Doc. # 4885]. *See also* Plaintiff's Memorandum in Support of Motion to Exclude Certain Opinions of Patrick J. Marshalek ("Memorandum").

Plaintiff seeks to exclude two categories of Dr. Marshalek's opinions: (1) those related to pharmacy practice and dispensing obligations; and (2) those related to the conduct of federal regulators and whether federal regulators caused or contributed to the "opioid catastrophe".[1] Memorandum at 1. Dr. Marshalek's opinions in these areas should not be excluded because they are sufficiently rooted in his extensive experience as a healthcare provider, healthcare administrator, and DEA consultant, and his testimony is reliably applied to the facts of this opioid litigation.

[1] Plaintiff does not define the term "opioid catastrophe" anywhere in its Memorandum. Kroger does not condone nor accept the use of this vague terminology by the Plaintiff. Therefore, the term "opioid catastrophe" in this Opposition is used only in reference to Plaintiff's Memorandum.

Dr. Marshalek is an accomplished medical doctor, certified by the American Board of Psychiatry and Neurology in Psychiatry and Addiction Medicine, with over twelve years of clinical experience treating patients – many of which suffer from opioid use disorder. He has more than fifteen years of experience as a DEA-registered controlled substance prescriber. Marshalek's Curriculum Vita at 1, attached as Exhibit A; Marshalek Dep. 37, attached as Exhibit B. He possesses a strong academic and medical research background as an Assistant Professor at the West Virginia University School of Medicine's Department of Behavioral Medicine & Psychiatry. Ex. A at 1. Furthermore, he possesses an extensive background in healthcare administration, serving as either Medical Director or Co-Medical Director at several healthcare facilities over the past ten years, including the West Virginia University Center for Integrative Pain Management. *Id.* at 2.

Dr. Marshalek is not a pharmacist, and he does not profess to be an expert with respect to *all* federal regulations applicable to the practice of pharmacy. Ex. B at 12-13. However, Dr. Marshalek, as a practicing "clinician with prescriptive authority" and healthcare administrator, regularly interacts with pharmacists and pharmacies. Ex. B at 16. Additionally, like pharmacists and pharmacies, Dr. Marshalek is registered with the DEA to dispense controlled substances, including prescription opioids. *See* 21 U.S.C. § 822(a)(2) (requiring that every person who "dispenses" controlled substances must obtain a registration from the DEA). Pharmacists and prescribers, like Dr. Marshalek, share the same mandate to provide "effective controls and procedures to guard against theft and diversion of controlled substances" under the implementing regulations of the Controlled Substances Act. 21 C.F.R. § 1301.71. Therefore, Dr. Marshalek possesses significantly more knowledge about the federal regulation of controlled substances and the responsibility to prevent diversion than the average layperson.

LEGAL STANDARD

The Court in Track One noted that, when ruling on motions to exclude expert testimony, the Court will apply the standards set forth in Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *In re Nat'l Prescription Opiate Litig.*, No. 17-MD-2804-DAP, 2019 WL 3934597, at *1 (N.D. Ohio Aug. 20, 2019). The Court recognized its role as a "gatekeeper" of expert testimony and noted that, as gatekeeper, it must "strike a balance between a liberal admissibility standard for relevant evidence on the one hand and the need to exclude misleading 'junk science' on the other." *Id.* (citing *Ask Chems., LP v. Computer Packages, Inc.*, 593 F. App'x 506, 509 (6th Cir. 2014) (quotations omitted).

In *Daubert*, the Supreme Court noted that the baseline rule for admissibility of evidence in federal courts is Federal Rule of Evidence 402, which provides: "All relevant evidence is admissible, except as otherwise provided by the Constitution, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority." *Daubert*, 509 U.S. 579 at 587 (quoting Fed. R. Evid. 402). Rule 401 defines "Relevant evidence" as evidence which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. The Court in *Daubert* noted that the basic standard of relevance in Rule 401 is "a liberal one" requiring the "general requirement of admissibility" of evidence under Rule 402. *Id.*

Rule 702 governs the admissibility of expert witness testimony specifically, and requires the expert to be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. In determining whether expert testimony is admissible, a court should consider three factors: (1) a proposed expert must have the requisite qualifications; (2) the proposed testimony must be relevant; and (3) the proposed testimony must be reliable. *In re Nat'l Prescription Opiate Litig.*,

2019 WL 3934597 at *2 (citing *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008)). Additionally, "rejection of expert testimony is the exception, rather than the rule." *Id.* (citing quoting Fed. R. Evid. 702, advisory committee notes).

ARGUMENT

Plaintiff does not claim that Dr. Marshalek's opinions fail to meet the broad definition of "Relevant evidence" under Rule 401, the "general requirement of admissibility" under Rule 402, or the relevancy and reliability requirements for expert testimony. Indeed, Dr. Marshalek's expert report offers reliable, relevant opinions concerning a variety of topics that are central to this case, including his first-hand experience as a clinician treating opioid addiction, and his experience witnessing the unintended consequences casting a wide net of blame upon stakeholders in the healthcare system, including pharmacies and opioid distributors. Marshalek Report at 3, attached as Exhibit C. The Court should not exclude any of Dr. Marshalek's opinions because the Federal Rules of Evidence broadly favor admissibility, his opinions are reliable, and they are relevant to the facts of this case.

Plaintiff does challenge the admissibility of certain opinions of Dr. Marshalek on the sole basis that he allegedly lacks the requisite qualifications to testify regarding "pharmacies and pharmacists' dispensing of opioids" and the "federal regulation of the opioid industry." Memorandum at 4. The Court should deny Plaintiff's request because Dr. Marshalek's opinions are based on his expertise as a medical doctor who treats patients with opioid use disorder and as a prescriber of controlled substances. Furthermore, Dr. Marshalek explains how his experience leads to his conclusions regarding these topics, and his experience can be reliably applied to the facts in this case. Additionally, as an experienced DEA consultant, academic, and controlled

substance prescriber, Dr. Marshalek is aptly qualified to offer his opinions regarding the regulation of the opioid industry by the DEA and other federal agencies.

I. Dr. Marshalek possesses the requisite knowledge and experience to offer opinions regarding pharmacies and pharmacists' dispensing of opioids.

Plaintiff grossly mischaracterize Dr. Marshalek's opinions concerning pharmacies and pharmacists and asserts that, because Dr. Marshalek stated at his deposition that he was not familiar with some of the federal laws surrounding the regulation of pharmacies or a few of the concepts related to a pharmacy's scope of practice, he is not qualified to provide any opinions concerning pharmacies and pharmacists' dispensing of opioids. Specifically, Plaintiff claims that Dr. Marshalek has "no demonstrated knowledge in the practice of pharmacy" because he allegedly lacks "aware[ness] of 'corresponding responsibility'" and was unable to describe the undefined concepts of "red flag" and "due diligence." Memorandum at 5.

Plaintiff uses terms such as "red flags" frequently in this litigation in advocating for its position. Dr. Marshalek need not utilize or condone the use of these terms of persuasion. Furthermore, the idea that because Dr. Marshalek is unfamiliar with some of the regulations applicable to the practice of pharmacy and the dispensing of opioid medications, he is not qualified to testify about pharmacists or pharmacies dispensing opioid medication *at all*, is broadly exclusionary and unsupported by case law. This Court has found that "regardless of the basis for the expert's qualifications[,] . . . a 'proffered expert may be unfamiliar with pertinent statutory definitions or standards [and this] is not grounds for disqualification. Such lack of familiarity affects the witness'[s] credibility, not his qualifications to testify.'" *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at *2 (citing *Davis v. Combustion Engineering, Inc.*, 742 F.2d 916, 919 (6th Cir. 1984). *See also First Tennessee Bank Nat. Ass'n v. Barreto*, 268 F.3d 319, 333 (6th Cir. 2001) (unfamiliarity with only some aspects of banking relationships merely affects weight and

credibility, not admissibility); *Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 296 (6th Cir. 2007) (expert with experience with the threat management unit of the Los Angeles Police Department was qualified to testify despite his lack of specific experience in commercial bus line threat assessment).

Plaintiff is free, through "vigorous cross examination," to attack the credibility of Dr. Marshalek's opinions regarding pharmacies and pharmacists. *Id.* (citing *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 376 (6th Cir. 2014) (quoting *Daubert*, 509 U.S. at 596). This Court should not "serve as a replacement for the adversary system" by excluding Dr. Marshalek's testimony related to pharmacies and pharmacists' dispensing of opioids. *See Burgett*, 579 F. App'x 372 at 376 (quoting Fed. R. Evid. 702, advisory committee notes).

As further evidence that Dr. Marshalek allegedly lacks the requisite experience with pharmacists' dispensing practices, Plaintiff cites an out-of-context quotation from his deposition and alleges Dr. Marshalek said he was not sure how pharmacists can question the legitimacy of a prescription. Memorandum at 5 (citing Ex. B at 156). However, Plaintiff fails to mention that immediately thereafter, upon further questioning, Dr. Marshalek clarified that from his experience as a clinician, he believes that pharmacists are at a distinct disadvantage to question whether a prescription for opioids was written for a legitimate medical purpose because the pharmacist was not present when the prescription was written and would not know if the patient was actually examined by a medical doctor or simply handed the prescription by office staff. Ex. B at 157. Here, Dr. Marshalek offers a clinician's perspective regarding what he foresees as the difficulties pharmacists face when identifying the legitimacy of an opioid prescription. Dr. Marshalek's expertise as a clinician with more than twelve years of experience as a prescriber of controlled

substances is "helpful to the trier of fact" to better understand the difficulties pharmacists face when dispensing opioids and other controlled substance prescriptions. *See* Fed. R. Evid. 702(a)(2).

Finally, the Plaintiff specifically takes issue with the following opinions in Dr. Marshalek's report related to pharmacies and pharmacists' opioid dispensing: (1) "[T]he pharmacists' scope of practice and situation downstream from the medical decision making and informed consent process prevent and limit their ability to question the legitimacy of prescriptions, and if they were ordered in the course of routine medical practice"; and (2) "To suggest that community pharmacies, or the pharmacists working for those community pharmacies, are responsible for the crisis of addiction is wrong." Memorandum at 1 (citing Ex. C at 3). However, once again, Plaintiff fails to read these opinions within the context of Dr. Marshalek's entire report.

Dr. Marshalek, as a healthcare provider and particularly as a healthcare administrator, possesses a great knowledge of the United States healthcare system, which serves as the basis for his expertise and the core theories behind his opinions. His opinion that the pharmacists' position downstream from the prescriber prevents and *limits* the pharmacists' ability to question the legitimacy of prescriptions is wholly based on his knowledge, as a medical doctor, that pharmacists are unable to engage in the process of informed consent in patient examination that medical doctors enjoy. Ex. C at 3. Dr. Marshalek also never claims that pharmacists have *no* means of questioning the legitimately of prescriptions. He merely notes the disadvantages pharmacists face – the inability to thoroughly vet patients for signs of addiction or prescription opioid abuse.

Dr. Marshalek's opinion that it is wrong to assign blame to community pharmacies or pharmacists for the addiction crisis similarly stems from his knowledge and experience that pharmacists and pharmacies are far downstream from entities like the federal government, who although had the authority and means to act, failed to do so, which ultimately contributed to a crisis

of opioid overdose deaths. Ex. C at 3. *See also id.* n.23 (citing the Standford-*Lancet* Commission's Report). *See also infra* Part II. Dr. Marshalek mentions several steps that federal regulators and others failed to take, which would have, in his opinion, reversed the increasing number of opioid deaths. Therefore, Dr. Marshalek's ultimate conclusion, that blaming pharmacies or pharmacists for the "addiction crisis" is wrong, is based on his opinion that pharmacists and pharmacies were not in the same position of power and influence as the federal government and other parties.

Again, if Plaintiff disagrees with Dr. Marshalek's conclusion, Plaintiff is free to cross-examine him. However, this Court should not strip away the trier of fact's ability to weigh the credibility of the evidence. *See McCullock v. H.B. Fuller Co*., 61 F.3d 1038, 1044 (2d Cir. 1995) (arguing that attacks on the expert's background, qualifications, use of accepted methodology, or lack of textural authority should be considered by the jury in assessing the weight to be accorded to the expert's testimony).

Therefore, this Court should reject's Plaintiff's attempts to exclude Dr. Marshalek's opinions concerning pharmacies, pharmacists, and opioid dispensing.

II. Dr. Marshalek possesses the requisite knowledge and experience to offer opinions regarding regulation of the opioid industry by federal agencies.

Plaintiff also contends that Dr. Marshalek does not have the requisite knowledge or expertise to assert his opinions "about the role of the DEA, FDA, and other federal agencies that are responsible for regulating the opioid industry." Memorandum at 8. Plaintiff takes particular issue with (1) the section of his opinion that discusses "several regulatory actions that DEA and FDA may take with respect to controlled substances"; and (2) his opinion that "[f]ar upstream from the busy prescriber, pharmacist, and community pharmacy sat those with power and ability to limit the overall amount of prescriptions that ultimately contributed to the epidemic of overdose deaths." *Id.* at 8-9 (citing Ex. C at 6). However, as an experienced DEA consultant, a controlled substance

prescriber registered with the DEA, and an academic, Dr. Marshalek is more than qualified to assert these opinions.

Plaintiff once again mischaracterizes Dr. Marshalek's opinions, in this instance, regarding the ability of federal regulators to limit the number of opioid prescriptions, stating that Dr. Marshalek "seems to place all responsibility for the opioid epidemic squarely on federal agencies while absolving prescribers, pharmacists, and pharmacies." Memorandum at 9. Dr. Marshalek is free to hold and offer this opinion. However, Dr. Marshalek's report specifically states that federal regulators *contributed* to the epidemic of overdose death, not that federal regulators are the sole cause. *See* Ex. C at 6. Indeed, Dr. Marshalek admitted at his deposition that, from his experience as a DEA consultant in connection with "pill mills,"[2] he believes that pill mill prescribers and community pharmacies connected with pill mills also contributed to the overdose epidemic. Ex. B at 155.

Dr. Marshalek's opinion concerning the ability of federal regulators to limit the supply of prescription opioids is based on his personal experience working with the DEA as a consultant, and his opinion is properly supported by his citation to the Standford-*Lancet* Report. *See* Ex. C at 3, n.23. Plaintiff erroneously contends that "Nowhere does the [Standford-*Lancet* Report] echo the proposition for which Dr. Marshalek cites it."[3] Memorandum at 8, n.9. However, the Standford-*Lancet* Report examines the "US and Canadian opioid crisis" as a "case study in multi-system *regulatory* failure." Humphreys et al., 399 Lancet 555, at 566, attached as Exhibit D (emphasis

[2] The term "pill mill" is typically used to describe a doctor, clinic, or pharmacy that is prescribing or dispensing controlled prescription drugs inappropriately. Rigg, Khary K et al. "Prescription Drug Abuse & Diversion: Role of the Pain Clinic." *Journal of drug issues* vol. 40,3 (2010): 681-702 at 681.

[3] Further, Plaintiff's assertion that the Standford-*Lancet* Report comments "on the pharmaceutical industry's success at 'regulatory capture'—i.e., getting corporate interest prioritized over the public interest," is irrelevant to Kroger. Memorandum at 8, n.9 (quoting Humphreys et al., *supra* n.2). Kroger did not influence, nor has Plaintiff produced any evidence that Kroger influenced, the federal or state regulation of prescription opioids.

added). The Standford-*Lancet* Report further cites several federal agency failures that contributed to the alleged opioid epidemic. *See id.* at 568 ("[H]ad the [FDA] conducted marketing studies of the many approved opioid medications been promptly done, the risks of addiction would have come to light more quickly . . ."). Regardless, here again, Plaintiff is questioning the accuracy of Dr. Marshalek's conclusion, which is not a proper basis for this Court to exclude his opinions. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597 at *2 ("[C]hallenges to the accuracy of an expert's conclusions or factual basis generally 'bear on the weight of the evidence rather than on its admissibility.'") (quoting *United States v. L.E. Cookie Co.*, 991 F.2d 336, 342 (6th. Cir. 1993)).

Finally, Plaintiff erroneously asserts that Dr. Marshalek "opines cursorily on several regulatory actions that the DEA and FDA may take with respect to controlled substances," while overlooking Dr. Marshalek's references and his own experience. Memorandum at 8. Dr. Marshalek cites sources in support of his opinions that the DEA failed to timely and accurately reschedule certain prescription opioid medications,[4] the FDA could have required better REMS programs,[5] and the DEA could have better utilized the training requirement for buprenorphine waivers.[6] Ex. C at 6. More important, as a prescriber of opioids, Dr. Marshalek must be familiar with applicable REMS programs;[7] and Dr. Marshalek obtained his Buprenorphine waiver in 2008 (Ex. A at 1).

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[4] *See* Ex. C at n.20 (Usmani SA, Hollmann J, Goodin A et al. Effects of hydrocodone rescheduling on opioid use outcomes: A systematic review. *J Am Pharm Assoc.* 2021;61(2):e20-e44).

[5] *See id*. at n.21 (*Center for Drug Evaluation and Research. Risk evaluation and mitigation strategies (REMS*). U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems. Published December 17, 2021. Accessed December 8, 2022).

[6] See *id*. at n.22 (*Become a buprenorphine waivered practitioner*. SAMHSA. Published April 21, 2022. Accessed December 8, 2022) (further citations omitted).

[7] "The REMS [Risk Evaluation and Mitigation Strategy] requires that training be made available to all health care providers (HCPs) who are involved in the management of patients with pain, including nurses and pharmacists." *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, U.S. Food and Drug Administration.

CONCLUSION

For these and other reasons apparent to the Court, Plaintiff's Motion to Exclude Certain Opinions of Patrick J. Marshalek should be denied with prejudice

Dated: March 9, 2023

Respectfully submitted,

The Kroger Co., Kroger Limited Partnership I, Kroger Limited Partnership II,

By counsel,

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https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems, attached hereto as Exhibit E. Current as of September 27, 2018. Accessed March 7, 2023.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on March 9, 2023, the foregoing document was filed with the Clerk of Court using the CM/ECF system which will send notice to all counsel of record. Copies of this document may be obtained through the CM/ECF system.

/s/ Ronda L. Harvey
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